

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Steven Shak Serial No.: To Be Assigned (Cont. Appln SN 09/669,306 filed September 25, 2000) Filed: 25 September 2000 For: ANTI-INFECTIVE THERAPY	Group Art Unit: 1651 Examiner: WITZ, j. <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on </div> <div style="text-align: center; margin-top: 10px;"> November 7, 2001  Aida Guiam </div>
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J1036 U.S. PTO
 10/005675
 11/07/01

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement:

- (a) accompanies the new patent application submitted herewith. 37 CFR §1.97(a).
- (b) is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491.
- (c) as far as is known to the undersigned, is filed before the mailing date of a first Office action on the merits. Should any fee be due, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$240.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account.
- (d) is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and is accompanied by either the fee (\$240) set forth in 37 CFR

§1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below. Should any fee be due, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$240.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. A duplicate of this sheet is enclosed.

- (e) is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$130) set forth in 37 CFR §1.17(i) and a statement as specified in 37 CFR §1.97(e), as checked below. **This document is to be considered as a petition requesting consideration of the information disclosure statement.** The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$130.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. A duplicate of this sheet is enclosed.

[If either of boxes (d) or (e) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.] The undersigned states that:

- Each item of information contained in the information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

A list of the patent(s) or publication(s) is set forth on the attached Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith:

- each none only those listed below:

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/669,306, filed September 25, 2000, and relied upon in this application for an earlier filing date under 35 USC §120.

- BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the GenBank and Dayhoff databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-0" (GenBank) and "BLAST Results B-1 - B-0" (Dayhoff) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration

of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

- not given
- given for each listed item
- given for only non-English language listed item(s) [Required]
- in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

The Examiner is reminded that a "concise explanation of the relevance" of the submitted prior art "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention," MPEP §609.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR §1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR §1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR §1.98 and MPEP §609 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,
GENENTECH, INC.

Date: November 7, 2001
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*A copy of a document pursuant to 37 C.F.R. § 10.9(b) is attached as proof of the authorization of the above to prosecute the attached application. The original of this document is on file in the Office of Enrollment and Discipline.

FORM PTO-1449				U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P0530P1C10	Serial No. To Be Assigned	
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)				Applicant Shak, Steven	Filing Date 07 Nov 2001	Group 1651	
U.S. PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	* 1	2,801,956	06.08.57	Baumgarten et al.			24.08.54
	* 2	2,834,710	13.05.58	Baumgarten et al.			29.06.55
	* 3	3,208,908	28.09.65	Maxwell et al.			16.11.61
	* 4	3,663,690	16.05.72	Eichel et al.			12.08.69
	* 5	4,065,355	27.12.77	Khouw et al.			08.10.76
	* 6	5,279,823	18.01.94	Frenz et al.			08.06.92
OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)							
	* 7	Andersson, H., "A double-blind randomized comparison of the effect and tolerance of varidase versus saline when instilled in the urinary bladder in patients with catheter problems" <u>J. Int. Med. Res.</u> 14(2):91-94 (1986)					
	* 8	Ayvazian et al., "The Use of Parenterally Administered Pancreatic Deoxyribonuclease as an Adjunct in the Treatment of Pulmonary Abscesses" <u>Am. Rev. of Tuberculosis and Pulmonary Diseases</u> 76(1):1-21 (July 1957)					
	* 9	Bendig, "The production of foreign proteins in mammalian cells" <u>Genetic Engineering</u> 7:91-127 (1988)					
	* 10	Cliffton et al., "Pancreatic Deoxyribonuclease (Dornase) Aerosol in Treatment of Bronchopulmonary Complications and Tracheitis Sicca" <u>Cancer</u> 14(2):414-420 (March-Apr 1961)					
	* 11	Contreras et al., "Effect of Plastic Containers on Liquid Preservation of Human Granulocytes. I. With and Without Deoxyribonuclease and Hydrocortisone" <u>Transfusion</u> 20(5):519-530 (Sept.-Oct 1980)					
	* 12	Deckert, T., "The immunogenicity of new insulins" <u>Diabetes</u> 34 (Supplement 2):94-96 (1985)					
	* 13	Doctor, V.M., "Studies on the Purification and Properties of Human Plasma Deoxyribonuclease I" <u>Archives of Biochem. and Biophysics</u> 103:286-290 (1963)					
	* 14	Farber et al., "Enzymatic Debridement" <u>J. of Thoracic Surgery</u> pps. 45-54 (1953)					
	* 15	Funakoshi et al., "Clinical Studies on Human Pancreatic Deoxyribonuclease I" <u>Japanese Society of Gastroenterology</u> 14(1):48-54 (February 1979)					
	* 16	Funakoshi et al., "Purification and Properties of Human Pancreatic Deoxyribonuclease I" <u>J. Biochem.</u> 82(6):1771-1777 (1977)					
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	* 18	Graham et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5" <u>J. Gen. Virol.</u> 36:59-72 (1977)					
	* 19	Hoover Remington's Pharmaceutical Sciences, Mack Publishing Co. pps. 972-973 (1975)					
	* 20	Hubbard et al., "A Preliminary Study of Aerosolized Recombinant Human Deoxyribonuclease I in the Treatment of Cystic Fibrosis" <u>New England J. of Medicine</u> 326(12):812-815 (March 19, 1992)					
	* 21	Ito et al., "Human Urine DNase I: Immunological Identity with Human Pancreatic DNase I, and Enzymic and Proteochemical Properties of the Enzyme" <u>J. Biochem.</u> 95(5):1399-1406 (1984)					
Examiner					Date Considered		
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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*22	Johnson et al., "The Intravenous Injection of Bovine Crystalline Pancreatic Desoxyribonuclease into Patients" <u>J. Clin. Invest.</u> 33:1670-1686 (1954)			
*23	Liao et al., "Bovine Pancreatic Deoxyribonuclease A" <u>Journal of Biological Chemistry</u> 248(4):1489-1495 (1973)			
*24	Liao, Ta-Hsiu, "Bovine Pancreatic Deoxyribonuclease D" <u>Journal of Biological Chemistry</u> 249:2354-2356 (1973)			
*25	Liao, Ta-Hsiu, "Multiple forms of deoxyribonuclease I" <u>Mol. and Cell. Biochem.</u> 34:15-22 (1981)			
*26	Lieberman, Jack, "Dornase Aerosol Effect on Sputum Viscosity in Cases of Cystic Fibrosis" <u>Journal of the American Medical Assn.</u> 205(5):114-115 (July 29, 1968)			
*27	Lourenco et al., "Clinical Aerosols. II. Therapeutic Aerosols" <u>Arch. Intern. Med.</u> 142:2299-2308 (Dec 1982)			
*28	Love et al., "The Relationship between Human Serum and Human Pancreatic DNase I" <u>J. of Biol. Chem.</u> 254(24):12588-12594 (December 25, 1979)			
*29	The Merck Index (Abstract 2890), Budavari et al., Eleventh edition, Rahway, NJ:Merck & Co., Inc. pps. 457 (1989)			
*30	Murai et al., "Purification and Properties of Deoxyribonuclease from Human Urine" <u>Biochimica et Biophysica Acta</u> 517:186-194 (1978)			
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*32	Nefsky et al., "Preparation of immobilized monomeric actin and its use in the isolation of protease-free and ribonuclease-free pancreatic deoxyribonuclease I" <u>European Journal of Biochemistry</u> 179:215-219 (1989)			
*33	Old & Primrose <u>Principles of Gene Manipulation: an introduction to genetic engineering</u> pps. 99-101 (Blackwell Scientific 1987)			
*34	Paudel et al., "Comparison of the Three Primary Structures of Deoxyribonuclease Isolated from Bovine, Ovine, and Porcine Pancreas" <u>J. of Biol. Chem.</u> 261(34):16012-16017 (December 5, 1986)			
*35	Paudel et al., "Purification, Characterization, and the Complete Amino Acid Sequence of Porcine Pancreatic Deoxyribonuclease" <u>J. of Biol. Chem.</u> 261(34):16006-16011 (December 5, 1986)			
*36	Potter et al., "The Composition of Pulmonary Secretions from Patients With and Without Cystic Fibrosis" <u>Am. J. Dis. Child.</u> 100:493-495 (1960)			
*37	Quaas et al., "Expression of the chemically synthesized gene for ribonuclease T1 in Escherichia coli using a secretion cloning vector" <u>European Journal of Biochemistry</u> 173:617-622 (1988)			
*38	Raskin, Philip, "Bronchospasm After Inhalation of Pancreatic Dornase" <u>Am. Rev. of Respiratory Disease</u> 98:697-698 (1968)			
*39	Rosenstreich et al., "A Human Urine-Derived Interleukin 1 Inhibitor" <u>Journal of Experimental Medicine</u> (Abstract #55-131389(A)) 168:1767-1779 (November 1988)			
*40	Salnikow et al., "Bovine Pancreatic Deoxyribonucleases A and C" <u>J. of Biol. Chem.</u> 248(5):1499-1501 (March 10, 1973)			
*41	Salomon et al., "Aerosols of Pancreatic Dornase in Bronchopulmonary Disease" <u>Annals of Allergy</u> pps. 71-79 (Jan.-Feb. 1954)			
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*42	Sasada et al., "Secretion of human EGF and IgE in mammalian cells by recombinant DNA techniques; use of a IL-2 leader sequence" <u>Cell Struct. Funct.</u> 13(2):129-141 (1988)			
*43	Segal et al., "Pancreatic Dornase Aerosols in Bronchopulmonary Disease" <u>Annals N.Y. Acad. Sci.</u> 68:138-143 (1957)			
*44	Seiyaku, Amano, "Deoxyribonuclease I purification by contacting liq. contg. mammalian pancreas extract with DNA fixed on agaroseat pH 4-5 and eluting by raising ionic strength" <u>Dialog Information Services, Dialog Accession No. 002567012, WPI Acc. NO. 80-85035C/198048</u> (1998)			
*45	Seiyaku, Amano, "Patent Abstracts of Japan" <u>Abstract of JP 55-131389</u> (Abstract only) 5(4):C 38 (October 13, 1980)			
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*47	Shields et al., "Cloning of part of the gene for bovine deoxyribonuclease I" <u>Biochemical Society Transactions</u> 16:195-196 (1988)			
*48	Suggs et al., "Use of Synthetic Oligonucleotides as Hybridization Probes: Isolation of Cloned cDNA Sequences for Human β_2 -Microglobulin" <u>Proc. Natl. Acad. Sci. USA</u> 78(11):6613-6617 (November 1981)			
*49	Takahara et al., "The ompA signal peptide directed secretion of staphylococcal nuclease A by Escherichia coli" <u>Journal of Biological Chemistry</u> 260(5):2670-2674 (1985)			
*50	Wang et al., "Preparation of Protease-free and Ribonuclease-free Pancreatic Deoxyribonuclease" <u>J. of Biol. Chem.</u> 253(20):7216-7219 (October 25, 1978)			
*51	Whittaker et al., "Isolation and characterization of four adenovirus type 12-transformed human embryo kidney cell lines" <u>Molecular Cell Biology</u> 4(1):110-116 (1984)			
*52	Wilson et al., "Immunogenicity of highly purified bovine insulin: a comparison with conventional bovine and highly purified human insulins" <u>Diabetologia</u> 28(9):667-670 (1985)			
*53	Wroblewski et al., "Presence of Desoxyribonuclease Activity in Human Serum" <u>P.S.E.B.M.</u> 74:443-445 (1950)			
*54	Yeager, Jr., Henry, "Tracheobronchial Secretions" <u>Am. J. of Medicine</u> 50:493-509 (April 1971)			
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